

## ISSUE PAPER

### EU White Paper: Strategy for a Future Chemicals Policy

**ISSUE:** The EU Commission presented a White Paper in February 2001, proposing a new strategy for regulating chemicals. The White Paper aims to create a single system for both existing and new, general industrial chemicals. The proposal will have a major impact on U.S. chemical companies exporting to and/or operating in Europe because of the expanded universe of chemicals covered and because of the extensive testing and reporting requirements to complete registration, evaluation, and authorization of substances subject to the new regimen. As proposed, the system will also affect downstream users of chemical products who export an intermediate or final product to Europe. Toys and textiles have been specifically identified as final products of concern.

#### POINTS THEY MAY RAISE

- As you may know, the EU chemical industry accounts for 29% of world chemical production [the United States accounts for 31%] and is Europe's third largest manufacturing industry. While there are numerous benefits to having such a strong chemical industry, there are also concerns about its effects on the environment and human health.
- 'Existing' chemicals comprise more than 99% of the total volume of all substances on the market (approximately 100,000 chemicals). These substances are not subject to as extensive a set of testing requirements as are 'new' substances. The lack of knowledge about the properties, uses, and impact of these existing substances on human health and the environment is a cause for concern. This new system will address these areas of concern and insure that manufacturers, importers, and downstream users of chemicals will be responsible for all aspects of the safety of their products.
- While we are working to ensure a high level of protection for our citizens, we are also working to maintain and enhance the competitiveness of the EU chemical industry and to prevent fragmentation of the internal market. We also want to be sure that there is conformity with EU obligations under the WTO such that there are no unnecessary barriers to trade and there is no discrimination against imported substances and products. We believe that the system as proposed will improve the competitiveness of the EU chemical industry without creating obstacles to trade.

#### POINTS YOU SHOULD RAISE

- We appreciate the opportunity the Commission has afforded all stakeholders, including U.S. companies, to provide comments on the proposed Strategy. The participation of Messrs. Donkers [Environment Directorate] and Schulte-Braucks [Enterprise Directorate] in the recent TABD Chemicals Working Group meeting is a clear indication of the willingness of the Commission to actively engage in dialogue on this subject.

- The United States is concerned that the White Paper will have significant consequences for the chemicals industry, especially the U.S. as world leader in chemicals production. Specific industry concerns include: the data requirements for registration, testing, and authorization; the cost burden for these requirements; the implications for intellectual property; the potential for bans of particular substances; and, the application of the system to constituents of products. This list is by no means exhaustive; I just want to highlight a few areas of particular concern.
- We appreciate your efforts to create a system that enhances the competitiveness of your industry while preventing market fragmentation. However, we are concerned that the dynamics of the system proposed will have the unintended effect of impeding innovation and creating an administrative and cost burden that small and medium-sized enterprises are incapable of bearing. As SMEs represent 96% of the total number of chemical enterprises in Europe, accounting for 28% of chemical production, I am sure that you share our concerns.
- As you are aware, the United States forwarded a preliminary set of questions on the Strategy to the Commission in December. We had the opportunity for bilateral dialogue on the Strategy and our questions in January and found it to be very productive. It is important for the United States and the EU to address trade concerns at an early stage to prevent them from escalating. We would welcome the opportunity for continuing dialogue on the Strategy as it is being developed and look forward to your responses to the questions we have raised.
- As I noted earlier, the TABD Chemicals Working Group met on this issue in mid-January and raised a number of concerns with the White Paper that we believe could be fruitfully addressed in talks between our experts. We would like to continue the involvement and dialogue of the TABD and other industry groups, as we believe they can be helpful in finding common ground between our two governments.

## BACKGROUND

### European Union

The EU is pursuing a new system for regulating chemicals because the current system simply does not work. It is inefficient, administratively burdensome, and costly to the Member States...among other things. Compounding this problem is the perception on the part of the general public that the Commission is failing to fulfill its obligation to protect its citizenry from substances and situations that can compromise human health and the environment (e.g., BSE). The politics of the EU at this point in time favor precaution over science and hazard assessment over risk assessment and politics, not science and not common sense, has every chance of dictating the nature and requirements of the new system. At the end of it all is a desire to put the obligation on industry for assuring the penultimate safety of their products throughout their useful life and beyond. It is possible that a proposal for a regulation could be finalized as early as June of this year though the expectation is that the measure will not be offered until

September.

Because the European chemicals industry is an 'export' industry, it is critical that they have other economies adopt their or a similar approach to chemicals management. Otherwise the EU industry would be severely disadvantaged. To that end, the Commission has been shopping the strategy directly to economies and in various international fora as a means of 'globally' managing chemicals. It is anticipated that the Commission will push for adoption of a global chemicals strategy at the World Summit for Sustainable Development using the White Paper, or their legislative language, as the model for international adoption.

#### United States/Industry

The U.S. chemicals industry has been slow to respond to the White Paper. Some companies/associations have delayed their response until they see definitive legislative language. Other have delayed comments because of a desire to have a 'global' response to chemicals management as opposed to a response to the EU text. The American Chemistry Council drafted a preliminary set of concerns with the Strategy in January but have not finalized the text and forwarded it to the Commission. To our knowledge, no company or association has forwarded recommendations for improving the Strategy to the Commission.

Despite this apparent lethargy, the industry is nonetheless concerned about the Strategy and has shared with Commerce Department and the U. S. Trade Representative's Office their concerns, their recommendations for improvement, and their analysis of the impact of the proposal on U.S. exports. Senior representatives from U.S. chemical companies are meeting on February 12, in London, to develop a position on the White Paper and a strategy for moving forward.

#### United States/Government

Since its presentation in February 2001, Commerce and USTR have been actively meeting with the U.S. chemicals industry to solicit their views and concerns regarding the White Paper. Commerce and USTR have met with representatives from the Synthetic Organic Chemical Manufacturers Association (SOCMA), the American Chemistry Council (ACC), the American Plastics Council, ISAC 3, DuPont, and Dow to identify industry concerns. Officials from the U.S. Mission in Brussels have also met with a number of European and U.S. chemical companies based in Europe to solicit their views on the Strategy and its impact on their industry. The USG has advised industry to develop an official position and strategy as soon as possible to assist in influencing the EU's draft text.

Because of the slow pace of industry response to the Strategy and growing concerns about trade effects and the influence of the Strategy on international environmental programs/activities for chemicals, Commerce, USTR, and EPA drafted a preliminary set of questions on the Strategy and provided them to the Commission in December. USTR also met with Commission officials at that time. Commerce, USTR, and EPA participated in the Transatlantic Business Dialogue Chemical Working Group meeting in January and followed-up the meeting with a bilateral on the Strategy that was very productive.

## TALKING POINTS

- THE U.S. IS STILL VERY CONCERNED THAT THE EUROPEAN UNION WILL ADOPT THE EU WHITE PAPER ON CHEMICALS IN THE NEAR FUTURE.
- IT IS IMPORTANT FOR THE U.S. AND GERMANY TO ADDRESS TRADE CONCERNS AT AN EARLY STAGE TO PREVENT THEM FROM ESCALATING INTO MAJOR DISPUTES. WE UNDERSTAND THAT THE NEW CHEMICAL STRATEGY COULD ALSO HAVE A NEGATIVE IMPACT ON EU CHEMICAL AND PHARMACEUTICAL COMPANIES THEREFORE IT IS IMPERATIVE THAT WE WORK TOGETHER ON THIS SIGNIFICANT ISSUE.
- RECENTLY, THE U.S. GOVERNMENT SENT OUT A DEMARCHE TO EU MEMBER STATES REQUESTING THEIR POSITION ON THE NEW CHEMICAL STRATEGY. HAS ANYONE IN YOUR GOVERNMENT RESPONDED? IF NOT, WHEN CAN WE EXPECT A RESPONSE?
- WE ENCOURAGE OPEN TECHNICAL DIALOGUE ON SPECIFIC CHEMICAL ISSUES SUCH AS HEALTH AND RISK ASSESSMENT, NOTIFICATION OF NEW SUBSTANCES AND MUTUAL ACCEPTANCE OF HEALTH AND ENVIRONMENTAL TEST DATA.

## **STATUS**

In recent meetings with the Commission, they indicated interest in discussing this further, perhaps in a break-out session at the October TABD CEO Conference in Stockholm. Commerce staff from TD and MAC have met with the American Chemistry Council and the American Plastics Council and have consulted with individual chemical companies to solicit their views on the strategy and its impact on the U.S. chemicals industry and European chemicals trade. FCS and the U.S. Mission in Brussels has also met with a number of U.S. chemical companies based in Europe.

USEU/FCS has informed TD/MAC that the Commission has begun drafting legislation related to the Chemicals White Paper. In their view it is imperative that the U.S. Government begin a dialogue with the EU on the strategy as soon as possible with the hope of influencing the draft text. TD/MAC has begun work with EPA and State to coordinate a USG position on the strategy and a series of questions regarding its proposed operation and effect on US/EU chemicals trade.

## **TALKING POINTS**

- THE U.S. IS VERY CONCERNED THAT THE EUROPEAN UNION WILL ADOPT THE EU WHITE PAPER ON CHEMICALS IN THE NEAR FUTURE.
- WE REQUEST THAT THE EU ADDRESS U.S. CONCERNS ON THE EU WHITE PAPER AND OPEN TECHNICAL DIALOGUE ON SPECIFIC CHEMICAL ISSUES SUCH AS HEALTH AND RISK ASSESSMENT, NOTIFICATION OF NEW SUBSTANCES AND MUTUAL ACCEPTANCE OF HEALTH AND ENVIRONMENTAL TEST DATA.
- THE TRANSATLANTIC BUSINESS DIALOGUE (TABD) INTRODUCED THIS AS IMPORTANT ISSUE DURING ITS MID YEAR MEETING IN MAY. TABD HAS BEEN VERY ACTIVE IN HELPING GOVERNMENTS ON BOTH SIDES SEEK COMMON GROUND ON THESE TYPE OF ISSUES.
- IT IS IMPORTANT FOR THE U.S. AND THE EU TO ADDRESS TRADE CONCERNS AT AN EARLY STAGE TO PREVENT THEM FROM ESCALATING TO MAJOR DISPUTES. WE LOOK FORWARD TO WORKING WITH THE EU COMMISSION AND THE MEMBER STATES ON THIS SIGNIFICANT ISSUE.

On May 21, the U.S. and EU engaged in a stakeholders conference in Brussels which addressed the issues of the Chemical White Paper. During the recent conference, we understand that Environmental Commissioner (DG-XI) Margot Wallstrom introduced the idea of organizing a public consultation once the proposals are ready and before they are formally adopted. She and Enterprise Commissioner Eriki Liikenen are scheduled to meet in near future to further discuss this event. Commissioner Liikenen supports this initiative and U.S. industry looks forward to using this initiative as an opportunity to provide further comments on the upcoming legislation. Commission representatives have publicly stated to U.S. officials they would welcome comments from third countries until legislation was adopted. The Commission has acknowledged that there are still a number of issues that need to be resolved, particularly on the role of downstream users and the impact on animal testing, particularly in the manufacturing of cosmetics and pharmaceuticals.

In January, the Transatlantic Business Dialogue Chemicals Working Group met to discuss issues related to the EU Chemical White Paper and the development of a new system for regulating chemicals. At the meeting held in Brussels, the EU announced that working groups, composed of Member States, industry and NGO's had been established and were aiding in the drafting process of the new legislation. The working groups have been developing comments on registration cost analysis, and risk assessment. However, the results have been very disappointing. In addition, U.S. Government participants from the Commerce Department, U.S. Environmental Protection Agency (EPA), State Department, and U.S. Trade Representatives (USTR) met separately with EU Commission officials to express U.S. concerns related to the development of the new Chemicals legislation related to transparency, risk assessment and mutual acceptance of existing chemicals.

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- WE ENCOURAGE OPEN TECHNICAL DIALOGUE ON SPECIFIC CHEMICAL ISSUES SUCH AS HEALTH AND RISK ASSESSMENT, NOTIFICATION OF NEW SUBSTANCES AND MUTUAL ACCEPTANCE OF HEALTH AND ENVIRONMENTAL TEST DATA.